UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Angela Dawn Cantrell,

Plaintiff,

v.

Coloplast Corp. and Coloplast Manufacturing US, LLC,

Defendants.

Case No. 20-cv-0672 (WMW/JFD)

ORDER

Before the Court are Defendants Coloplast Corp. and Coloplast Manufacturing US, LLC's (collectively, Coloplast) motion for summary judgment, (Dkt. 43), and motions to exclude the opinions and testimony of Plaintiff Angela Dawn Cantrell's six experts, (Dkts. 48, 54, 60, 66, 72, 78). For the reasons addressed below, Coloplast's motions to exclude expert opinions and testimony are granted in part and denied in part, and Coloplast's motion for summary judgment is granted.

BACKGROUND

Cantrell is a resident of the state of California. Coloplast is a Delaware corporation with its principal place of business in Minnesota. Coloplast manufacturers and markets the Restorelle L, a surgical mesh device for use in the treatment of vaginal vault prolapse.

In January 2018, Cantrell's doctor implanted the Restorelle L mesh as a part of a surgery to correct Cantrell's vaginal prolapse. Cantrell continued to experience pain and pelvic floor dysfunction after the surgery and underwent several additional surgeries.

In March 2020, Cantrell commenced this action, advancing eleven claims to relief. Coloplast now moves for summary judgment as to all of Cantrell's claims. Coloplast also moves to exclude the opinions and testimony of Cantrell's six expert witnesses. Cantrell opposes Coloplast's motions to exclude the opinions and testimony of Cantrell's expert witnesses but only contests Coloplast's motion for summary judgment as to three of her eleven claims: negligent design (Count I), design defect (Count II), and failure to warn (Count III).

ANALYSIS

I. Coloplast's Motions to Exclude Expert Testimony

Coloplast moves to exclude the opinions and testimony of Dr. Alan Garely, Dr. Jimmy Mays, Dr. Peggy Pence, Dr. Susan Theut, Dr. Bruce Rosenzweig, and Dr. William Gold.

The admissibility of expert testimony is an issue of law for the district court to decide and is governed by Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and

> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. "An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed." Fed. R. Evid. 703. "If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted." *Id.*

The proponent of expert testimony must prove its admissibility by a preponderance of the evidence. *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001). "Rule 702 reflects an attempt to liberalize the rules governing the admission of expert testimony" and favors admissibility over exclusion. *Id*. (internal quotation marks omitted). Determinations as to the admissibility of expert testimony are within a district court's discretion. *See Arkwright Mut. Ins. Co. v. Gwinner Oil, Inc.*, 125 F.3d 1176, 1182 (8th Cir. 1997).

A district court must ensure that testimony admitted under Rule 702 "is not only relevant, but reliable." *Daubert*, 509 U.S. at 589. When making this reliability determination, a court may evaluate whether the expert's method has been tested or subjected to peer review and publication, the method's known or potential rate of error, and the method's general acceptance. *Presley v. Lakewood Eng'g & Mfg. Co.*, 553 F.3d 638, 643 (8th Cir. 2009) (citing *Daubert*, 509 U.S. at 593–94). These factors are not exhaustive, and a court must evaluate the reliability of expert testimony based on the facts of the case. *Id.* A court also may consider "whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the proposed expert

ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case." *Sappington v. Skyjack, Inc.*, 512 F.3d 440, 449 (8th Cir. 2008) (internal quotation marks omitted). When weighing these factors, a district court must function as a gatekeeper to separate "expert opinion evidence based on 'good grounds' from subjective speculation that masquerades as scientific knowledge." *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001).

Expert testimony is not admissible if it is "speculative, unsupported by sufficient facts, or contrary to the facts of the case," *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757 (8th Cir. 2006), such that it is "so fundamentally unsupported that it can offer no assistance to the jury," *Minn. Supply Co. v. Raymond Corp.*, 472 F.3d 524, 544 (8th Cir. 2006) (internal quotation marks omitted). But disputes about the factual basis of an expert's testimony ordinarily implicate the credibility—not the admissibility—of the testimony. *Sappington*, 512 F.3d at 450; *see also Minn. Supply Co.*, 472 F.3d at 544.

A. Alan Garely, M.D.

Coloplast moves to exclude the testimony of Dr. Alan Garely. Dr. Garley is a urogynecologist and seeks to opine that Coloplast's transvaginal pelvic organ prolapse (POP) products are defectively designed, the implantation of Coloplast transvaginal POP products does not result in superior functional outcomes, and Coloplast knew about problems with its transvaginal POP products. Coloplast's central objection is that Dr. Garely's opinion is limited to mesh implanted transvaginally, not transabdominally.

Coloplast argues that, as a result, Dr. Garely's opinion does not encompass Restorelle L, the mesh implant at issue in this case, which was implanted transabdominally in Cantrell.

Expert witnesses must provide a written report that contains "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). "The disclosure mandates in Rule 26 are given teeth by the threat of sanctions in Rule 37." *Vanderberg v. Petco Animal Supplies Stores, Inc.*, 906 F.3d 698, 702 (8th Cir. 2018). Federal Rule of Civil Procedure 37 provides that, "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1).

Dr. Garely's expert report provides that it "pertains to Coloplast's polypropylene products indicated for transvaginal placement for pelvic organ prolapse." Dr. Garely's expert report specifies the products encompassed by the report, which include "Restorelle (Smartmesh) Transvaginal Products," but does not include Restorelle L, the product at issue in this case.

In *Mathison v. Boston Scientific Corp.*, the United States District Court for the Southern District of West Virginia concluded that expert testimony from an expert whose report addressed a similar product but failed to address the product at issue in the case was admissible and relevant because the defendant had "failed to demonstrate any material distinctions between" the two products. No. 2:13-cv-05851, 2015 WL 2124991, at *19 (S.D.W. Va. May 6, 2015). Here, Cantrell contends that Dr. Garely's opinions

pertain to the properties of mesh, not the method by which the mesh is implanted. And Dr. Garely's expert report indicates that Coloplast uses the same mesh for all of its Restorelle products. But the opinions encompassed in Dr. Garely's report pertain specifically to the risks inherent in transvaginal *implantation* of pelvic-mesh implants.[1]

Dr. Garely's deposition testimony also suggests that there *are* material distinctions between the transvaginal and transabdominal mesh implants. Dr. Garely testified that comparing abdominal and vaginal placement of the same mesh is "like comparing apples to oranges," and that the mesh "behave[s] completely differently in one space than it does in another." Because there are material distinctions between the mesh based on where it is implanted, any testimony by Dr. Garely as to Restorelle L, a mesh implant indicated for transabdominal implantation, was not properly disclosed pursuant to Rule 27(a)(2)(B)(i). Moreover, because the opinions in Dr. Garely's expert report pertain only to transvaginal implantation, Dr. Garely's testimony would be unhelpful to a jury. *See Daubert*, 509 U.S. at 591 (observing that Rule 702 "requires that the evidence or testimony assist the trier of fact to understand the evidence or to determine a fact in issue" (internal quotation marks omitted)). Accordingly, the Court grants Coloplast's motion to exclude Dr. Garely's expert testimony.

B. Jimmy Mays, Ph.D.

Coloplast moves to exclude the opinions and testimony of Dr. Jimmy Mays. Dr. Mays seeks to opine on the properties of polypropylene, the material used in the

[1] Coloplast provided an incomplete copy of Dr. Garely's expert report and Cantrell has not supplemented the report. The Court, therefore, relies only on the opinions expressed in the excerpt Coloplast provided.

Restorelle L mesh, the degradation undergone by polypropylene in the body, and the effects of such degradation. Coloplast argues that Dr. Mays's opinions are unreliable, Dr. Mays lacks the expertise and qualifications necessary to testify, and Dr. Mays's opinions are not relevant to Cantrell's alleged injuries.

1. Reliability

Dr. Mays seeks to testify that the surface layer of mesh implants degrades in the body as a result of "an inflammatory response called the 'foreign body reaction.' " Coloplast argues that Dr. Mays's opinion is unreliable because peer-reviewed literature contradicts Dr. Mays's hypothesis that the body degrades polypropylene.

Expert testimony is not admissible if it is "speculative, unsupported by sufficient facts, or contrary to the facts of the case," *Marmo*, 457 F.3d at 757, such that it is "so fundamentally unsupported that it can offer no assistance to the jury," *Minn. Supply Co.*, 472 F.3d at 544 (internal quotation marks omitted). But disputes about the factual basis of an expert's testimony ordinarily implicate the credibility—not the admissibility—of the testimony. *Sappington*, 512 F.3d at 450; *see also Minn. Supply Co.*, 472 F.3d at 544.

Coloplast relies on a peer-reviewed paper by Dr. Shelby Thames, which concludes that the original extrusion lines of the fiber from which the mesh is made are visible after sufficient cleaning. According to Dr. Thames, the fact that the original extrusion lines are visible suggests that the surface layer of the fiber does not degrade within the body. Dr. Mays's expert report addresses and criticizes Dr. Thames's article but does not

address its finding that the extrusion lines of the fiber are visible after cleaning.[2] And although Dr. Mays cursorily addressed the extrusion-line argument at his deposition, he testified that he was unaware of any publications challenging Thames's findings. But "*Daubert* neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance." *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998). And a dispute such as the one between Dr. Mays and Dr. Thames is fodder for cross-examination. *See Damgaard v. Avera Health*, 104 F. Supp. 3d 983, 987 (D. Minn. 2015) ("At bottom, [the party challenging admissibility] will have ample opportunity at trial to explore the challenged opinions, including the factual bases upon which they rest, through '[v]igorous cross-examination' and the 'presentation of contrary evidence.' " (quoting *Daubert*, 509 U.S. at 596)). For these reasons, the Court denies Coloplast's motion to exclude Dr. Mays's opinions and testimony as to the possibility that the surface layer of mesh implants degrades in the body.

Coloplast also argues that Dr. Mays lacks a reliable basis for his opinion that the human body continues to release oxidants for the entire life of a mesh implant. The United States District Court for the Northern District of Florida, considering the same argument, concluded that "Dr. Mays'[s] conclusion overreaches the limits set by the authors of the article on which he relies." *Arevalo v. Coloplast Corp.*, No. 3:19cv3577-TKW-MJF, 2020 WL 3958505, at *6 (N.D. Fla. July 7, 2020). In his expert report,

[2] Coloplast provided an incomplete copy of Dr. Mays's expert report and deposition testimony, and Cantrell has not supplemented the report. The Court, therefore, relies only on the opinions expressed in the excerpt Coloplast provided.

Dr. Mays states that "polypropylene . . . is continually attacked by strong oxidizing agents inside the body." But one of the sources upon which Dr. Mays relies instead suggests that the "rate of release of powerful chemicals from activated cells" markedly decreases after an "acute inflammatory phase." And Dr. Mays testified at his deposition that "it is not known" whether the cells secreting oxidizing agents "remain activated or become quiescent." For this reason, the Court grants Coloplast's motion to exclude Dr. Mays's opinion that the body "continually" releases oxidizing agents. But because Dr. Mays is a polymer scientist with extensive experience studying polypropylene, Dr. Mays's testimony as to the general principles of polymer degradation in the body is admissible. *See Arevalo*, 2020 WL 3958505, at *6 (concluding that Dr. "Mays may testify generally about the mechanism by which oxidizing agents can deplete antioxidant stabilizers in polypropylene thereby leading to oxidation").

Dr. Mays also seeks to rely on an analysis of a different company's mesh implants. Coloplast argues that Dr. Mays's testing of a different company's mesh implants is an unreliable basis for his opinions on Coloplast's mesh implants. Cantrell concedes that Dr. Mays did not perform testing on Coloplast's products. Instead, Cantrell contends, Dr. Mays will testify about mesh degradation based on his experience and his review of the literature. Dr. Mays has a Ph.D. in polymer science and extensive experience analyzing and working with polypropylene. Because Dr. Mays has experience with polypropylene generally but did not perform testing on Coloplast's mesh in particular, Dr. Mays may testify as to the general process of mesh degradation. Dr. Mays may not testify about the specific properties of Coloplast's mesh.

Dr. Mays also seeks to testify that the antioxidants used to prevent degradation of the mesh "may prove toxic to the human body" based on the material safety data sheets (MSDS) for the raw materials used to make Coloplast's surgical mesh implants. Coloplast argues that Dr. Mays's opinions based on the MSDS are unreliable because he cannot say what quantity of antioxidants would be toxic, and because he is not a toxicologist or pathologist. Cantrell contends that Dr. Mays should be allowed to testify based on the MSDS, to the extent that they constitute a basis for his opinions on degradation, an assertion that Coloplast does not appear to challenge. Accordingly, Dr. Mays may testify based on the MSDS to the extent that they constitute a basis for his opinions on degradation. But because Dr. Mays is neither a pathologist nor a toxicologist, Coloplast's motion to exclude his opinion that the antioxidants used to prevent degradation may be toxic based on Coloplast's surgical mesh MSDS is granted.

2. Qualifications and Expertise

Dr. Mays seeks to opine that oxidative degeneration of mesh causes an increase in the stiffness of the mesh, and that such stiffness can cause pain. Coloplast argues that Dr. Mays is not qualified to testify about this subject because he cannot quantify the amount of stiffness that results from degeneration and how much stiffness would be necessary to produce clinical symptoms. Dr. Mays conceded during his deposition that he was not qualified to quantify the amount of stiffness, which he agreed would be necessary to understand the effect of the stiffness on the human body. Coloplast's motion to exclude Dr. Mays's testimony and opinions, therefore, is granted as to his opinions on the effects of stiffening mesh on the human body.

Coloplast also argues that, because he is not a medical doctor, Dr. Mays is unqualified to testify as to clinical complications. Cantrell contends that Dr. Mays's qualifications as a polymer scientist render him qualified to testify to clinical complications but concedes that Dr. Mays "would be unqualified to dive deep into the clinical realm." "The proponent of the expert testimony must prove its admissibility by a preponderance of the evidence." *Lauzon*, 270 F.3d at 686. Because Cantrell has not established that Dr. Mays has the requisite qualifications to testify as to clinical complications from the implantation of surgical mesh, Coloplast's motion to exclude Dr. Mays's testimony as to clinical complications is granted.

3. Relevance

Coloplast argues that Dr. Mays's opinions on degradation should be excluded in their entirety because there is no evidence that Cantrell's mesh implant degraded in her body. Cantrell contends that "polypropylene degradation is the primary reason Plaintiff submits that Coloplast's polypropylene meshes are defective and unreasonably dangerous." Rule 702 "requires that the evidence or testimony 'assist the trier of fact to understand the evidence or to determine a fact in issue.' " *Daubert*, 509 U.S. at 591 (quoting Fed. R. Evid. 702). Because the issue of polypropylene degradation is central to the case, Dr. Mays's testimony as to how polymers degrade is relevant. Accordingly, Coloplast's motion to exclude Dr. Mays's opinions on polypropylene degradation as irrelevant is denied, subject to the limits on admissibility addressed above.

In summary, Coloplast's motion to exclude is granted as to Dr. Mays's opinions and testimony as to whether the body continually releases oxidizing agents, the specific

properties of Coloplast's mesh, the toxicity of the antioxidants used to prevent mesh degradation, the effects of stiffening mesh on the human body, and clinical complications. Coloplast's motion to exclude Dr. Mays's testimony is denied in all other respects.

C. Peggy Pence, Ph.D.

Dr. Pence seeks to opine that Coloplast did not conduct adequate clinical testing of its pelvic-mesh implants, failed to disclose known safety risks in the instructions for use (IFUs) for its pelvic-mesh implants, and failed to perform adequate post-market surveillance in accordance with industry standards. Coloplast argues that Dr. Pence's testimony should be excluded because (1) she provides narrative, unhelpful summaries of internal documents; (2) she is unqualified to opine on regulation of medical devices or industry standards; (3) her proposed testimony is based mostly on non-Restorelle devices; (4) her proposed testimony as to the adequacy of Coloplast's testing is unreliable; (5) her proposed testimony about Restorelle's IFUs is unreliable; (6) her proposed testimony about post-marketing surveillance is unreliable and irrelevant; and (7) her proposed testimony about Coloplast's disclosures to the FDA is inconsistent with federal law.

1. Summaries of Coloplast's Internal Documents

Coloplast argues that Dr. Pence merely summarizes Coloplast's internal documents without providing any additional information that would be helpful to a jury. Cantrell contends that a summary of corporate documents can be admissible and helpful if such a summary is not improper state-of-mind testimony.

Rule 702 "requires that the evidence or testimony 'assist the trier of fact to understand the evidence or to determine a fact in issue.' " *Daubert*, 509 U.S. at 591

(quoting Fed. R. Evid. 702). "Expert testimony is helpful to a jury if it concerns matters beyond the knowledge of average individuals; however, it cannot supplant the jury's role in evaluating the evidence." *United States v. Shedlock*, 62 F.3d 214, 219 (8th Cir. 1995). Other courts that have considered expert testimony in the context of polypropylene mesh products liability cases have concluded that a summary of internal corporate documents can be used to explain the basis for the expert's testimony but is not otherwise helpful to the jury. *See, e.g.*, *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013) (observing that a corporation's "knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury"); *Salinero v. Johnson & Johnson*, No. 1:18-cv-23643-UU, 2019 WL 7753453, at *18 (S.D. Fla. Sept. 5, 2019) (observing that "simply parroting documents or other testimony does nothing to assist the trier of fact").

Coloplast asserts that "[e]ntire pages of [Dr. Pence's] report are spent narrowly selecting quotes and snippets from company documents." As Coloplast has redacted the contents of these pages of Dr. Pence's report, the merit of Coloplast's argument is difficult to discern. But because a summary of internal corporate documents is not helpful to the jury, Coloplast's motion to exclude Dr. Pence's summary of internal corporate documents is granted, except to the extent Dr. Pence relies on the summary to establish the basis for her testimony.

2. Qualifications

Coloplast contends that Dr. Pence is not qualified to testify. A witness may be qualified as an expert based on the witness's knowledge, skill, experience, training, or education. Fed. R. Evid. 702; *David E. Watson, P.C. v. United States*, 668 F.3d 1008, 1014 (8th Cir. 2012). "[A]n expert might draw a conclusion from a set of observations based on extensive and specialized experience." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999); *accord Shuck v. CNH Am., LLC*, 498 F.3d 868, 875 (8th Cir. 2007) (recognizing that "observations coupled with expertise generally may form the basis of an admissible expert opinion"). Expert testimony may be excluded, however, when "there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

Coloplast argues that Dr. Pence is not qualified to testify about the adequacy of Coloplast's testing because Dr. Pence does not have a degree in a relevant field and has never performed a clinical trial for a pelvic-mesh device. Dr. Pence has a Ph.D. in toxicology, with a minor in pharmacology. Although Dr. Pence has not worked on a clinical trial for a female pelvic-mesh device, she has implemented other clinical trials throughout her career. Because Dr. Pence's lack of experience with pelvic-mesh devices specifically goes to the weight of her testimony, not its admissibility, Coloplast's motion to exclude the testimony and opinions of Dr. Pence is denied as to the adequacy of Coloplast's testing.

Coloplast also argues that Dr. Pence is not qualified to testify as to the scientific properties of polypropylene because she does not have any training or expertise in

chemical engineering or polymer science. "The proponent of the expert testimony must prove its admissibility by a preponderance of the evidence." *Lauzon*, 270 F.3d at 686. The record does not reflect that Dr. Pence has the qualifications necessary to testify about the scientific properties of polypropylene. Coloplast's motion to exclude Dr. Pence's testimony as to the scientific properties of polypropylene is, therefore, granted.

Coloplast argues that Dr. Pence is not qualified to testify about the adequacy of the warnings and IFUs for Coloplast's pelvic-mesh devices because Dr. Pence's career has focused on pharmaceutical development, not medical device development. Coloplast also argues that Dr. Pence is not qualified to testify about what warnings should be in the IFUs because she is not a surgeon. According to Coloplast, IFUs do not need to contain warnings commonly known to the surgeons who prescribe or implant the devices. And because Dr. Pence is not a surgeon, Coloplast argues, she is unqualified to say which risks must be disclosed in an IFU.

"Gaps in an expert witness's qualifications or knowledge generally go to the weight of the witness's testimony, not its admissibility." *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100 (8th Cir. 2006) (internal quotation marks omitted). Dr. Pence has extensive experience in clinical product development. Any gaps in her knowledge of the development of medical devices pertain to the weight of her testimony, not its admissibility. Coloplast's motion to exclude Dr. Pence's testimony as to the adequacy of the warnings and IFUs for Coloplast's pelvic-mesh devices is denied. But because Coloplast correctly observes that Dr. Pence is not a medical doctor, Coloplast's motion to

exclude Dr. Pence's testimony about the clinical background of the disorders treated with mesh products is granted.

Coloplast argues that Dr. Pence is not qualified to testify about Coloplast's post-marketing surveillance of its pelvic-mesh device because she did not work on any medical devices until she formed her consulting company and she has never performed any regulatory consulting for a pelvic-mesh device. But, as addressed above, Dr. Pence has significant experience in product development. Any gaps in her knowledge of medical devices or pelvic-mesh devices specifically pertain to the weight of her testimony, not its admissibility. Coloplast's motion to exclude Dr. Pence's testimony as to post-marketing surveillance is denied.

In summary, Coloplast's motion to exclude Dr. Pence's testimony on the basis of her qualifications is granted as to the scientific properties of polypropylene and the clinical background of the disorders treated with mesh products. Coloplast's motion to exclude Dr. Pence's opinions and testimony based on her qualifications is denied in all other respects.

3. Testimony Based on Non-Restorelle Devices

Coloplast argues that Dr. Pence should be precluded from testifying about any non-Restorelle devices because such testimony is not relevant. Cantrell maintains that testimony about all polypropylene mesh products is relevant because the mesh used in each device is the same, and because FDA regulations and industry standards do not differ based on the precise product at issue. Rule 702 "requires that the evidence or

testimony 'assist the trier of fact to understand the evidence or to determine a fact in issue.' " *Daubert*, 509 U.S. at 591 (quoting Fed. R. Evid. 702).

Some of Dr. Pence's expert report does not concern the specific properties of any particular device. One section's purpose "is to describe the globally recognized industry standards for the development of medical devices." Because this testimony is relevant to Cantrell's design-defect claims, Coloplast's motion to exclude Dr. Pence's testimony about global industry standards is denied.

In a section entitled "Clinical Background," Dr. Pence describes the clinical background of the disorders treated with mesh products. As addressed in Part I.C.2 of this Order, the Court excluded Dr. Pence's testimony as to the scientific properties of mesh and the clinical background of the disorders treated with mesh products. Dr. Pence's expert report also describes several "authoritative bodies" that support the need for clinical testing of mesh products. Because Coloplast has not provided any explanation for why such testimony would not be relevant to Restorelle mesh products, Coloplast's motion to exclude Dr. Pence's testimony about clinical testing of mesh products on this basis is denied.

4. Adequacy of Coloplast's Testing

Coloplast argues that Dr. Pence's testimony that Coloplast's testing was inadequate should be excluded as unreliable because Dr. Pence does not identify any regulation, rule, or standard that requires clinical trials. Cantrell maintains that Dr. Pence's testimony is not unreliable merely because she relies on non-binding industry standards. Expert testimony is not admissible if it is "speculative, unsupported by

sufficient facts, or contrary to the facts of the case," *Marmo*, 457 F.3d at 757, such that it is "so fundamentally unsupported that it can offer no assistance to the jury," *Minn. Supply Co.*, 472 F.3d at 544 (internal quotation marks omitted). Disputes about the factual basis of an expert's testimony ordinarily implicate the credibility—not the admissibility—of the testimony. *Sappington*, 512 F.3d at 450; *see also Minn. Supply Co.*, 472 F.3d at 544. When scrutinizing an expert's testimony about industry standards, "the relevant question for admissibility purposes" is not whether the standards are controlling, but instead "whether consulting them is a methodologically sound practice on which to base an expert opinion in the context of this case." *Lees v. Carthage Coll.*, 714 F.3d 516, 525 (7th Cir. 2013).

Dr. Pence devotes a section of her expert report to describing "the globally recognized industry standards for the development of medical devices." Dr. Pence describes the Global Harmonization Task Force (GHTF), which was "a partnership between regulatory authorities and the regulated medical device industry" and included the United States, European Union, Canada, Australia, and Japan. Dr. Pence explains various standards developed by the GHTF, including safety and performance standards, material standards, risk analysis and management systems, product verification and validation, clinical evaluation, and post-market surveillance. In the context of a products liability case, consulting industry standards—albeit ones that are nonbinding—is a methodologically sound practice. Whether the standards are binding or not goes to the weight of the testimony, not its admissibility. For this reason, Coloplast's motion to exclude Dr. Pence's testimony as to industry standards is denied.

5. Restorelle's Instructions for Use (IFUs)

Coloplast argues that Dr. Pence's proposed testimony about Restorelle's IFUs is unreliable and irrelevant, and that Dr. Pence is unqualified to provide testimony on a pelvic mesh IFU.

According to Coloplast, Dr. Pence's proposed testimony about Restorelle's IFUs is unreliable because Dr. Pence does not adequately explain the basis for her opinion and relies on an unreliable methodology to reach her conclusions. Expert testimony is not admissible if it is "speculative, unsupported by sufficient facts, or contrary to the facts of the case," *Marmo*, 457 F.3d at 757, such that it is "so fundamentally unsupported that it can offer no assistance to the jury," *Minn. Supply Co.*, 472 F.3d at 544 (internal quotation marks omitted). But disputes about the factual basis of an expert's testimony ordinarily implicate the credibility—not the admissibility—of the testimony. *Sappington*, 512 F.3d at 450; *see also Minn. Supply Co.*, 472 F.3d at 544.

Coloplast argues that Dr. Pence's opinions on Restorelle's IFU are unreliable because she bases her opinions on complications discussed in the medical literature, the FDA's Manufacturer and User Device Experience (MAUDE) database,[3] evaluations of pelvic mesh by the FDA and international bodies, clinical data from Coloplast documents, and internal Coloplast documents. Coloplast argues that these sources are insufficient

[3] The MAUDE database "houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers." U.S. Food and Drug Admin., *MAUDE – Manufacturer and User Facility Device Experience*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM (last visited June 24, 2022).

bases for Dr. Pence's opinions because they do not provide guidance about whether the complications found should be included in an IFU. But Dr. Pence devotes several pages of her expert report to explaining what information should be provided in the IFU based on the materials she considered. Because Coloplast's challenge to the bases for Dr. Pence's opinions goes to the weight of her testimony, not its admissibility, Coloplast's motion to exclude as unreliable Dr. Pence's testimony as to the contents of the IFUs is denied.

Coloplast also argues that Dr. Pence's testimony as to the Restorelle IFU is irrelevant because the adverse events reports she cites from the MAUDE database pertain to pelvic-mesh devices manufactured by Ethicon. Rule 702 "requires that the evidence or testimony 'assist the trier of fact to understand the evidence or to determine a fact in issue.' " *Daubert*, 509 U.S. at 591 (quoting Fed. R. Evid. 702). Adverse events reports pertaining to a different pelvic-mesh device are not relevant to this case and would not assist the trier of fact to understand the evidence or determine a fact in issue. Accordingly, Coloplast's motion to exclude Dr. Pence's testimony as to the Restorelle IFUs is granted in so far as Dr. Pence relies on data pertaining to Ethicon pelvic-mesh devices.

Dr. Pence is unqualified to testify about whether the Restorelle IFUs provide adequate information for surgeons to obtain informed consent, Coloplast argues, because she is not a surgeon and has never prepared an IFU for a pelvic-mesh device. The Court agrees. Because Dr. Pence is not a surgeon and has not offered any basis for opining on

this subject, Coloplast's motion to exclude Dr. Pence's testimony regarding informed consent is granted.

In summary, Coloplast's motion to exclude Dr. Pence's testimony and opinions about the Restorelle IFUs is granted as to informed consent and in so far as Dr. Pence relies on data pertaining to Ethicon pelvic-mesh devices. Coloplast's motion to exclude Dr. Pence's testimony and opinions about the Restorelle IFUs is denied in all other respects.

6. Post-Marketing Surveillance

Coloplast contends that Dr. Pence's opinions about Coloplast's post-marketing surveillance should be excluded as unreliable and irrelevant because the GHTF standards on which Dr. Pence bases her opinion are not binding and, therefore, are unreliable. As addressed above, standards that are non-binding may nonetheless constitute a sound basis for expert testimony. *See supra*, Part I.C.4. Coloplast's motion to exclude Dr. Pence's testimony as to post-marketing surveillance on this basis is denied.

Coloplast also argues that Dr. Pence's post-marketing surveillance opinions are unreliable because they rely on data contained in the FDA's MAUDE database, which houses medical device reports submitted by manufacturers, importers and device user facilities as well as from health care professionals and patients. Coloplast contends that the MAUDE database is not a reliable source for reaching scientific conclusions because the submissions are unverified.

The FDA's website explains that MAUDE, as a passive surveillance system, "has limitations," and notes that "the incidence, prevalence, or cause of an event cannot be

determined from this reporting system alone due to under-reporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency of device use." U.S. Food and Drug Administration, *Medical Device Reporting (MDR): How to Report Medical Device Problems*, https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems (last visited June 24, 2022). But Dr. Pence does not rely solely on MAUDE data for her opinions as to Coloplast's alleged failure to conduct adequate post-market surveillance. Instead, Dr. Pence references the information contained in the MAUDE database as only one source of information that Coloplast should consider.

Because such disputes about factual basis ordinarily pertain to weight and not admissibility, *Sappington*, 512 F.3d at 450, Coloplast's motion to exclude Dr. Pence's testimony based on her consideration of MAUDE data is denied.

7. Disclosures to the FDA

Coloplast argues that any testimony offered by Dr. Pence as to Coloplast's alleged failure to disclose information to the FDA should be excluded because any claim based on failure to disclose information to the FDA is contrary to federal law. Cantrell maintains that she has "no intention of discussing what Coloplast did or did not disclose to the FDA in seeking 510(k) clearance of its pelvic mesh products." Because there is no dispute between the parties to resolve at this time, the Court denies as moot Coloplast's motion to exclude testimony as to Coloplast's disclosures to the FDA.

D. Susan K. Theut, M.D., M.P.H.

Coloplast moves to exclude the testimony of Dr. Theut. Cantrell intends to offer Dr. Theut, a phsychiatrist, to opine that the implantation of the Restorelle L injured Cantrell's mental health. Coloplast argues that any testimony by Dr. Theut about causation at trial should be excluded because Dr. Theut does not offer any opinion that the psychiatric diagnoses listed in her expert report were caused by the Restorelle L.

Witnesses "retained or specially employed to provide expert testimony" must provide a written report that contains "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). "The disclosure mandates in Rule 26 are given teeth by the threat of sanctions in Rule 37." *Vanderberg*, 906 F.3d at 702. Federal Rule of Civil Procedure 37 provides that, "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1).

Dr. Theut's expert report provides a summary of Dr. Theut's interview with Cantrell, a mental status examination, a diagnostic impression and discussion, and Dr. Theut's recommendations. The only connection Dr. Theut makes between the mesh implantation and Cantrell's psychological health is a comment that Cantrell is "only 47 years old and her life has been altered drastically since the mesh was placed in 1-2018." Otherwise, the report describes Cantrell's self-reports of side effects from the Restorelle L implantation. Cantrell does not argue that the failure to disclose any opinion from

Dr. Theut regarding causation was substantially justified or harmless, and no justification is apparent from the record. Because Dr. Theut does not provide an opinion on causation, the Court grants Coloplast's motion to exclude Dr. Theut's testimony about whether the Restorelle caused psychological injury to Cantrell.

E. Bruce Rosenzweig, M.D.

Coloplast moves to exclude the testimony of Dr. Bruce Rosenzweig, a urogynecologist. Dr. Rosenzweig seeks to opine that Coloplast's transvaginal pelvic organ prolapse mesh products are unsuitable for permanent implantation, that their design is flawed and unsafe, that the warnings in the IFUs are inadequate, that Coloplast made misleading marketing claims about their mesh products, and that safer alternative designs exist.

1. Opinions on Transvaginal Mesh

Coloplast argues that, because Dr. Rosenzweig's opinions only pertain to transvaginally implanted surgical mesh, his opinions are irrelevant to this case, which concerns transabdominally placed mesh. Coloplast also argues that Dr. Rosenzweig's opinions should be excluded because they were not properly noticed under Rule 26. Cantrell responds that Dr. Rosenzweig's testimony pertains to the properties of polypropylene and the characteristics of mesh, which remain the same regardless of how the mesh is implanted.

Rule 702 "requires that the evidence or testimony 'assist the trier of fact to understand the evidence or to determine a fact in issue.' " *Daubert*, 509 U.S. at 591 (quoting Fed. R. Evid. 702). Witnesses "retained or specially employed to provide expert

testimony" must provide a written report that contains "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). "The disclosure mandates in Rule 26 are given teeth by the threat of sanctions in Rule 37." *Vanderberg*, 906 F.3d at 702. Federal Rule of Civil Procedure 37 provides that, "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1).

Some of Dr. Rosenzweig's opinions clearly pertain only to the implantation method, such as his opinion that "because of their transvaginal implantation design, the Coloplast transvaginal pelvic organ prolapse mesh products are not suitable for their intended application as a permanent prosthetic implant for pelvic organ prolapse." And at his deposition, when asked about a different pelvic mesh product indicated for abdominal implantation, Dr. Rosenzweig testified that "the opinions that I have in my report are regarding transvaginally-placed mesh." When asked additional questions about transabdominal mesh, he reiterated several times that he had not offered an opinion about the transabdominal mesh. Because Dr. Rosenzweig limited his opinions to transvaginal mesh, Cantrell did not properly notice any opinions from Dr. Rosenzweig regarding transabdominal mesh. *See Bayless v. Bos. Sci. Corp.*, No. 6:20-cv-831-Orl-37GJK, 2020 WL 10058191, at *3 (M.D. Fla. Dec. 7, 2020) ("Allowing Dr. Rosenzweig to offer general expert testimony on the design of [transabdominal mesh] at this late juncture would be unfair to Coloplast [and] would run contrary to Rule 26."). But Dr.

Rosenzweig offers other opinions that address the properties of the mesh itself. Such opinions, to the extent they are relevant to mesh that is implanted transabdominally, were properly noticed.

For these reasons, Coloplast's motion to exclude Dr. Rosenzweig's testimony and opinions is granted as to any testimony that pertains only to transvaginal mesh.

2. Safer Alternative Designs

Coloplast also challenges Dr. Rosenzweig's opinions as to safer alternatives as unreliable. Expert testimony is not admissible if it is "speculative, unsupported by sufficient facts, or contrary to the facts of the case," *Marmo*, 457 F.3d at 757, such that it is "so fundamentally unsupported that it can offer no assistance to the jury," *Minn. Supply Co.*, 472 F.3d at 544 (internal quotation marks omitted). But disputes about the factual basis of an expert's testimony ordinarily implicate the credibility—not the admissibility—of the testimony. *Sappington*, 512 F.3d at 450; *see also Minn. Supply Co.*, 472 F.3d at 544. Dr. Rosenzweig bases his opinion on his experience with many of the alternatives he suggests, in addition to his review of medical literature and other materials. Because disputes about factual basis go to weight, and not admissibility, Coloplast's motion to exclude Dr. Rosenzweig's testimony as to safer alternative designs as unreliable is denied.

Coloplast also argues that Dr. Rosenzweig's testimony as to safer alternative designs is irrelevant because the alternatives Dr. Rosenzweig describes are surgeries, not other medical devices. Rule 702 "requires that the evidence or testimony 'assist the trier of fact to understand the evidence or to determine a fact in issue.' " *Daubert*, 509 U.S. at

591 (quoting Fed. R. Evid. 702). A surgery is not a safer alternative design for a pelvic mesh product. *Cf. Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 943 (S.D.W. Va. 2017) ("[A]lternative surgeries or procedures concern the medical judgment of the doctors who use [the medical device to treat an issue]; other surgeries or procedures do not inform the jury on *how* the [device's] design could have feasibly been made safer to eliminate the risks that caused the plaintiffs' injuries."). For this reason, Coloplast's motion to exclude Dr. Rosenzweig's testimony as to any safer alternative designs that are not other medical devices is granted.

3. Opinions on "Blind Passage"

Coloplast moves to exclude Dr. Rosenzweig's testimony on the safety of "blind passage" implantation using needles or trocars because Cantrell's surgeon did not use needles or trocars to implant Cantrell's surgical mesh. Cantrell concedes that this evidence is not relevant to her design-defect claim. But she argues that Dr. Rosenzweig's testimony is relevant to Cantrell's negligence and punitive damage claims. Because the product at issue in this case does not require insertion through a "blind passage," such opinions are not relevant. Coloplast's motion to exclude Dr. Rosenzweig's testimony as to the safety of the "blind passage" implantation technique is granted.

4. Opinions on Small-Pore and Heavyweight Mesh

Coloplast also moves to exclude Dr. Rosenzweig's opinions that the mesh used in the Restorelle L is "small pore" or "heavyweight" as unreliable. Expert testimony is not admissible if it is "speculative, unsupported by sufficient facts, or contrary to the facts of the case," *Marmo*, 457 F.3d at 757, such that it is "so fundamentally unsupported that it

can offer no assistance to the jury," *Minn. Supply Co.*, 472 F.3d at 544 (internal quotation marks omitted). But disputes about the factual basis of an expert's testimony ordinarily implicate the credibility—not the admissibility—of the testimony. *Sappington*, 512 F.3d at 450; *see also Minn. Supply Co.*, 472 F.3d at 544. Dr. Rosenzweig supports his opinion on the characterization of the Coloplast mesh with multiple medical studies. Because disputes as to the factual basis of Dr. Rosenzweig's testimony go to credibility, and not admissibility, Coloplast's motion to exclude Dr. Rosenzweig's testimony as to the characteristics of Coloplast's mesh is denied.

5. Polypropylene Properties and Degradation

Coloplast challenges Dr. Rosenzweig's qualification to testify as to the properties of polypropylene, the mechanism by which degradation might occur, and the clinical effects of degradation. A witness may be qualified as an expert based on the witness's knowledge, skill, experience, training, or education. Fed. R. Evid. 702; *David E. Watson, P.C.*, 668 F.3d at 1014. "[A]n expert might draw a conclusion from a set of observations based on extensive and specialized experience." *Kumho Tire Co.*, 526 U.S. at 156; *accord Shuck*, 498 F.3d at 875 (recognizing that "observations coupled with expertise generally may form the basis of an admissible expert opinion"). Expert testimony may be excluded, however, when "there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146. "Gaps in an expert witness's qualifications or knowledge generally go to the weight of the witness's testimony, not its admissibility." *Robinson*, 447 F.3d at 1100.

Dr. Rosenzweig is a urogynecologist with experience with pelvic floor surgery. Dr. Rosenzweig also explains that the medical literature he reviewed to formulate his testimony is "consistent with what [he] ha[s] seen [in his] own clinical practice." Although the copy of Dr. Rosenzweig's report that Coloplast provides does not include a complete description of Dr. Rosenzweig's qualifications, other courts have found Dr. Rosenzweig qualified to testify about the properties of mesh based on his extensive clinical experience with pelvic floor surgeries. *See, e.g.*, *Wilkerson v. Bos. Sci. Corp.*, No. 2:13-cv-04505, 2015 WL 2087048, at *5 (S.D.W. Va. May 5, 2015) (observing that "although Dr. Rosenzweig may not know the precisions of oxidative degradation, Dr. Rosenzweig has demonstrated extensive knowledge of and experience with the process of polypropylene mesh degradation in the body. He has performed over a thousand pelvic floor surgical procedures, as well as close to 300 surgeries dealing with complications related to synthetic mesh" (internal quotation marks omitted)). This Court agrees. Coloplast's motion to exclude Dr. Rosenzweig's testimony as to the properties of mesh and the degradation process is denied to the extent that such knowledge is based on his personal experience as a clinician and review of the relevant literature.

Coloplast also argues that Dr. Rosenzweig's testimony on mesh degradation is unreliable and, therefore, inadmissible, because there is no reliable evidence that polypropylene degrades in the body. The Court has addressed this argument as it relates to Coloplast's motion to exclude the opinions and testimony of Dr. Mays. *See supra*, Part I.B.1. Because disputes about factual basis go to weight, and not admissibility,

Sappington, 512 F.3d at 450, Coloplast's motion to exclude Dr. Rosenzweig's testimony on degradation is denied.

6. State of Mind and Narrative Descriptions of Company Documents

Coloplast moves to exclude any testimony by Dr. Rosenzweig about Coloplast's state of mind, Coloplast's conduct or descriptions of Coloplast documents. Cantrell argues that Dr. Rosenzweig uses corporate documents "as a basis and to reinforce his opinions about the complications caused by Coloplast's mesh products." Rule 702 "requires that the evidence or testimony 'assist the trier of fact to understand the evidence or to determine a fact in issue.' " *Daubert*, 509 U.S. at 591 (quoting Fed. R. Evid. 702). "Expert testimony is helpful to a jury if it concerns matters beyond the knowledge of average individuals; however, it cannot supplant the jury's role in evaluating the evidence." *Shedlock*, 62 F.3d at 219. Other courts that have considered expert testimony in the context of polypropylene mesh products liability cases have concluded that a summary of internal corporate documents can be used to explain the basis for the expert's testimony but such testimony is not otherwise helpful to the jury. *See, e.g.*, *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 611 (observing that a corporation's "knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury"); *Salinero*, 2019 WL 7753453, at *18 (observing that "simply parroting documents or other testimony does nothing to assist the trier of fact"). Because testimony about Coloplast's state of mind and Coloplast's corporate conduct are not

helpful to the jury, Coloplast's motion to exclude Dr. Rosenzweig's testimony is granted as to testimony about Coloplast's state of mind and Coloplast's conduct, except to the extent these subjects provide the basis for Dr. Rosenzweig's opinions.

7. Design and Testing of Medical Devices

Coloplast argues that Dr. Rosenzweig is not sufficiently qualified to opine about the design and testing of medical devices. Cantrell argues that Dr. Rosenzweig has "substantial experience with testing genitourinary and pelvic medical devices." Cantrell represents that Dr. Rosenzweig was involved in the development of several products but does not point to any support for this experience in the record. As the proponent of Dr. Rosenzweig's expert testimony, Cantrell must prove its admissibility by a preponderance of the evidence. *Lauzon*, 270 F.3d at 686. Because Cantrell has not demonstrated that Dr. Rosenzweig has the requisite experience to testify as to the design or testing of the Restorelle L, Coloplast's motion to exclude Dr. Rosenzweig's testimony about design and testing of medical devices is granted.

In summary, Coloplast's motion to exclude Dr. Rosenzweig's opinions and testimony is granted as to any opinion or testimony that pertains to the following subjects: transvaginal mesh; alternative designs that are not other medical devices; the safety of the "blind passage" implantation technique; Coloplast's state of mind and Coloplast's conduct, except to the extent that such testimony regarding Coloplast's state of mind or conduct provides the basis for Dr. Rosenzweig's opinions; and the design and testing of medical devices. Coloplast's motion to exclude Dr. Rosenzweig's opinions and testimony is denied in all other respects.

F. William Gold, M.D.

Coloplast moves to exclude the expert testimony of Dr. William Gold. Cantrell intends to offer Dr. Gold to testify that (1) the Restorelle L injured Cantrell, (2) Coloplast's understanding of the biocompatibility of mesh implants is deficient, (3) Coloplast failed to perform adequate clinical testing on the Restorelle L, and (4) Coloplast does not adequately warn patients and physicians about the risks of the Restorelle L.

1. Foundation of Specific-Causation Opinions

Because Cantrell has failed to provide admissible general-causation testimony, Coloplast argues, Dr. Gold's testimony as to specific causation lacks foundation and is unreliable. Cantrell responds that Dr. Garely, Dr. Rosenzweig, and Dr. Mays all offer admissible expert testimony on which Dr. Gold can reasonably rely. The Court has admitted some of the testimony of Dr. Mays and Dr. Rosenzweig, and their admissible testimony constitutes sufficient general causation testimony to create a foundation for Dr. Gold's specific-causation testimony. Coloplast's motion to exclude Dr. Gold's testimony based on a lack of foundation for his general-causation opinions, therefore, is denied.

2. Qualifications

Coloplast challenges Dr. Gold's qualification to provide an expert opinion because he does not have experience or training in urogynecology or with surgical mesh implants. Cantrell contends that Dr. Gold has extensive experience in gynecology. A witness may be qualified as an expert based on the witness's knowledge, skill, experience, training, or

education. Fed. R. Evid. 702; *David E. Watson, P.C.*, 668 F.3d at 1014. "[A]n expert might draw a conclusion from a set of observations based on extensive and specialized experience." *Kumho Tire Co.*, 526 U.S. at 156; *accord Shuck*, 498 F.3d at 875 (recognizing that "observations coupled with expertise generally may form the basis of an admissible expert opinion"). Expert testimony may be excluded, however, when "there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146. "Gaps in an expert witness's qualifications or knowledge generally go to the weight of the witness's testimony, not its admissibility." *Robinson*, 447 F.3d at 1100. Dr. Gold is a medical doctor specializing in gynecology, with experience evaluating and surgically treating women with stress urinary incontinence. Any gaps in his qualifications or knowledge go to the weight of Dr. Gold's testimony, not its admissibility. Coloplast's motion to exclude Dr. Gold's testimony because Dr. Gold is unqualified is denied.

3. Reliability

Coloplast also moves to exclude Dr. Gold's testimony on the grounds that his methodology is unreliable. A district court has a "gatekeeping role" that requires it to separate "expert opinion evidence based on 'good grounds' from subjective speculation that masquerades as scientific knowledge." *Glastetter*, 252 F.3d at 989. Expert testimony must be excluded when "there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146.

Dr. Gold reviewed excerpts of Cantrell's medical records, published medical literature, testimony from experts pertaining to the topics at issue in the case, and publicly

available Coloplast materials. Dr. Gold concludes that Cantrell's symptoms were "caused by the defects in design, testing, and marketing of the Coloplast Restorelle L products she had implanted in January 2018" and describes her symptoms as "the result of her body's intrinsic foreign body reaction." But Dr. Gold does not explain how the materials he reviewed support his conclusion that Cantrell's symptoms were caused by the Restorelle L.[4] An impermissible "analytical gap," therefore, exists between the data and the opinion proffered. As the proponent of Dr. Gold's expert testimony, Cantrell must prove its admissibility by a preponderance of the evidence. *Lauzon*, 270 F.3d at 686. On the record before the Court, Cantrell has not established the reliability of Dr. Gold's expert testimony.

For the same reasons, Cantrell failed to properly notice Dr. Gold's expert opinion on causation. An expert report must contain "a *complete* statement of all opinions the witness will express and the basis and *reasons for them*." Fed. R. Civ. P. 26(a)(2)(B)(i) (emphasis added). If "a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). Here, although Dr. Gold provided the materials on which he relied and the conclusions he drew from them, he

[4] Cantrell attempts to supplement Dr. Gold's expert report with a declaration attached as an exhibit to its response in opposition to Coloplast's motion to exclude Dr. Gold's testimony. But Dr. Gold's declaration was submitted on December 20, 2021. Cantrell's deadline for disclosing expert reports was May 20, 2021. Cantrell may not supplement Dr. Gold's report more than six months after the disclosure deadline. Accordingly, the Court declines to consider Dr. Gold's declaration.

failed to provide the *reasons* for his opinions. Dr. Gold's failure to include the reasons for his opinions is neither substantially justified nor harmless. Because of the dearth of information in Dr. Gold's report, Coloplast would have no way to prepare to cross-examine him. *See Werth v. Hill-Rom, Inc.*, 856 F. Supp. 2d 1051, 1060 (D. Minn. 2012) ("The requirement to provide a report containing all bases for an expert's opinion is intended to permit opposing counsel to effectively prepare to depose the expert in advance of trial."); *accord Reed v. Binder*, 165 F.R.D. 424, 430 (D.N.J. 1996) ("Nothing causes greater prejudice than to have to guess how and why an adversarial expert reached his or her conclusion.").

For these reasons, the Court grants Coloplast's motion to exclude Dr. Gold's specific-causation testimony.

4. Properties of Polypropylene

Arguing that Dr. Gold is unqualified to provide such opinions, Coloplast moves to exclude Dr. Gold's testimony about the properties of polypropylene. Cantrell contends that Dr. Gold is qualified because he has reviewed reliable scientific literature on polypropylene. A witness may be qualified as an expert based on the witness's knowledge, skill, experience, training, or education. Fed. R. Evid. 702; *David E. Watson, P.C.*, 668 F.3d at 1014. Expert testimony may be excluded, however, when "there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146. Dr. Gold is an experienced gynecologist. But unlike Dr. Rosenzweig, Dr. Gold has no clinical experience with polypropylene mesh. Accordingly, Coloplast's

motion to exclude Dr. Gold's testimony as to the properties of polypropylene mesh is granted.

5. Clinical Trials and Adverse-Event Monitoring

Coloplast moves to exclude Dr. Gold's testimony regarding clinical trials and adverse-event monitoring because, Coloplast argues, Dr. Gold is not qualified to opine on those topics. Cantrell responds that Dr. Gold is qualified to opine because he has reviewed Dr. Pence's expert report. But Dr. Gold has no experience in product development or post-marketing surveillance. Coloplast's motion to exclude Dr. Gold's testimony as to clinical trials and adverse-event monitoring is granted.

6. Cantrell's Future Medical Needs

Coloplast moves to exclude Dr. Gold's testimony regarding Cantrell's future medical needs, arguing that Dr. Gold is unqualified to opine on that topic. Cantrell maintains that Dr. Gold is qualified through his experience as a professor of obstetrics and gynecology. Dr. Gold is an experienced gynecologist who has treated patients with similar symptoms to Cantrell. Because Dr. Gold has extensive gynecological experience, Coloplast's motion to exclude Dr. Gold's testimony about Cantrell's future medical needs is denied. *See Kumho Tire Co.*, 526 U.S. at 156 ("[A]n expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

7. Corporate Culture

Coloplast moves to exclude Dr. Gold's testimony about Coloplast's corporate culture as improper. Cantrell maintains that Dr. Gold will not provide any improper

state-of-mind testimony. Because there is no dispute as to this issue, Coloplast's motion to exclude Dr. Gold's testimony as to Coloplast's corporate culture is denied as moot.

In summary, Coloplast's motion to exclude the opinions and testimony of Dr. Gold is granted as to the specific causation of Cantrell's injuries, the properties of polypropylene mesh, and clinical trials and adverse-event monitoring. Coloplast's motion is denied in all other respects.

II. Choice of Law

The parties dispute which state's laws govern this dispute. A federal court sitting in diversity applies the choice-of-law rules of the forum state to determine which substantive law should apply. *See Heating & Air Specialists, Inc. v. Jones*, 180 F.3d 923, 928 (8th Cir. 1999). The Court must, therefore, apply Minnesota choice-of-law rules to determine which state's laws apply to Cantrell's claims. Coloplast contends that California law governs because Cantrell's alleged injury occurred in California. Cantrell maintains that Minnesota law governs because Cantrell commenced her action in Minnesota and because the product at issue was made and designed in Minnesota by a corporation with headquarters in Minnesota.[5]

[5] Cantrell initially argues that Coloplast waived its argument that California law applies. But the cases on which Cantrell relies are inapposite, because they pertain to choice-of-law arguments raised for the first time on appeal. *See P & O Nedlloyd, Ltd. v. Sanderson Farms, Inc.*, 462 F.3d 1015, 1017 n.3 (8th Cir. 2006) ("Because choice of law is waived if not timely raised, we need not address the choice of law question for the first time on appeal."); *Wiser v. Wayne Farms*, 411 F.3d 923, 926 (8th Cir. 2005) ("In the choice of law context, in particular, we repeatedly have refused to consider arguments not presented to the district court."); *Ortiz v. Gaston Cnty. Dyeing Mach. Co.*, 277 F.3d 594, 597 (1st Cir. 2002) (same). Cantrell's argument is unavailing.

Under Minnesota law, "[b]efore a choice-of-law analysis can be applied, a court must determine that a conflict exists between the laws of two forums." *Nodak Mut. Ins. Co. v. Am. Fam. Mut. Ins. Co.*, 604 N.W.2d 91, 93–94 (Minn. 2000) (footnote omitted). The parties do not dispute that there is a substantive conflict between California and Minnesota law. For example, although California law does not recognize strict-liability claims for implanted medical devices, *see Hufft v. Horowitz*, 5 Cal. Rptr. 2d 377, 384 (1992), Minnesota law does, *see Farr v. Armstrong Rubber Co.*, 179 N.W.2d 64, 69 (1970). An actual conflict exists between the laws of the two forums.

The Court must next consider whether the law of both states can be constitutionally applied, which requires that the state "must have a significant contact or significant aggregation of contacts, creating state interests, such that choice of its law is neither arbitrary nor fundamentally unfair." *Jepson v. Gen. Cas. Co. of Wis.*, 513 N.W.2d 467, 469 (Minn. 1994) (quoting *Allstate Ins. Co. v. Hague*, 449 U.S. 302, 313 (1981)). Here, Coloplast is headquartered in Minnesota and Cantrell resides in California. Therefore, significant enough contacts with both California and Minnesota exist such that applying either state's law is neither arbitrary nor fundamentally unfair.

Having determined that either state's law could be constitutionally applied, the Court next analyzes five choice-influencing factors: the "(1) predictability of result; (2) maintenance of interstate and international order; (3) simplification of the judicial task; (4) advancement of the forum's governmental interest; and (5) application of the better rule of law." *Jepson*, 513 N.W.2d at 470. In tort cases, the second and fourth factors are most important. *See Burks v. Abbott Lab'ys*, 639 F. Supp. 2d 1006, 1013 (D. Minn.

2009). As to the second factor, the Court considers "whether the application of Minnesota law would manifest disrespect for [the other state's] sovereignty or impede the interstate movement of people and goods." *Jepson*, 513 N.W.2d at 471. And "where a state has little or no contact with a case and nearly all of the significant contacts are with a sister state, the factor suggests that a state should not apply its own law to the dispute. *Hughes v. Wal-Mart Stores, Inc.*, 250 F.3d 618, 620–21 (8th Cir. 2001) (internal quotation marks omitted). Here, Cantrell resides in California and was implanted with the Restorelle L in California. This action's only contact with Minnesota is that Coloplast is headquartered in Minnesota. Accordingly, this factor weighs in favor of applying California law.[6]

As to the fourth factor, the Court considers "which choice of law most advances a significant interest of the forum." *Jepson*, 513 N.W.2d at 472. Cantrell argues that Minnesota has a significant interest in regulating the behavior of companies headquartered in its state and a significant interest in compensating tort victims. Coloplast argues that California has a significant interest in having the rights of its citizens adjudicated according to its own law. Both states have significant interests in litigating the matter. But because California has more extensive contacts with this case, the Court applies California law to this dispute.

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[6] Cantrell also claims, without support, that the Restorelle L is designed and manufactured in Minnesota. Coloplast provides evidence that the mesh used for Restorelle products is manufactured outside of the United States. And regardless of where the Restorelle L was designed, the second factor weighs in favor of applying California law because Cantrell's injury—which is at the heart of this dispute—occurred in California.

III. Summary Judgment

Summary judgment is proper when the record before the district court establishes that there is "no genuine dispute as to any material fact" and the moving party is "entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A genuine dispute as to a material fact exists when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). When deciding a motion for summary judgment, a district court construes the evidence in the light most favorable to the nonmoving party and draws all reasonable inferences in the nonmoving party's favor. *See Windstream Corp. v. Da Gragnano*, 757 F.3d 798, 802–03 (8th Cir. 2014). When asserting that a fact is genuinely disputed, the nonmoving party must "submit affidavits, depositions, answers to interrogatories, or admissions on file and designate specific facts" in support of that assertion. *Gander Mountain Co. v. Cabela's, Inc.*, 540 F.3d 827, 831–32 (8th Cir. 2008); *accord* Fed. R. Civ. P. 56(c)(1)(A). A nonmoving party may not "rest on mere allegations or denials but must demonstrate on the record the existence of specific facts which create a genuine issue for trial." *Krenik v. County of Le Sueur*, 47 F.3d 953, 957 (8th Cir. 1995) (internal quotation marks omitted).

Coloplast moves for summary judgment as to each of Cantrell's claims. Cantrell opposes summary judgment only as to her claims for negligent design (Count I), design defect (Count II), and failure to warn (Count III).

1. Negligent Design

Coloplast argues that Cantrell's negligent-design claim fails because Cantrell has not provided admissible specific-causation evidence. Under California law, a plaintiff

advancing product-liability claims must prove that a defect in the product caused injury. *See Brady v. Calsol, Inc.*, 194 Cal. Rptr. 3d 243, 246 (2015). A plaintiff must prove causation "within a reasonable medical probability based upon competent expert testimony." *Jones*, 209 Cal. Rptr. at 460. Here, the Court has excluded the specific-causation testimony of Dr. Theut and Dr. Gold, Cantrell's only specific-causation experts. Without admissible testimony supporting Cantrell's claim that the Restorelle L caused her injury, Cantrell cannot succeed on her negligent-design claim as a matter of law. Accordingly, Coloplast's motion for summary judgment as to Cantrell's negligent-design claim is granted.

2. Strict Liability Design Defect

Coloplast argues that Cantrell's strict-liability design-defect claim fails because Cantrell has not provided admissible specific-causation evidence. As addressed above, California law requires a plaintiff advancing product-liability claims to prove that a defect in the product caused injury. *See Brady*, 194 Cal. Rptr. 3d at 246. A plaintiff must prove causation "within a reasonable medical probability based upon competent expert testimony." *Jones v. Ortho Pharm. Corp.*, 209 Cal. Rptr. 456, 460 (1985). Here, the Court has excluded the specific-causation testimony of Dr. Theut and Dr. Gold, Cantrell's only specific-causation experts. Without admissible testimony supporting Cantrell's claim that the Restorelle L caused her injury, Cantrell cannot succeed on her strict-liability design-defect claim as a matter of law. Coloplast's motion for summary judgment as to Cantrell's strict-liability design-defect claim, therefore, is granted.

Even if the Court had not excluded the specific-causation testimony of Dr. Theut and Dr. Gold, Cantrell's strict-liability design-defect claim fails because California law does not allow a strict-liability claim for a design defect of a medical device. *See Hufft*, 5 Cal. Rptr. 2d at 384 ("We hold that a manufacturer is not strictly liable for injuries caused by an implanted prescription medical product which has been (1) properly made and (2) distributed with information regarding risks and dangers of which the manufacturer knew or should have known at the time."). Cantrell concedes that California law prohibits such claims. For these reasons, Coloplast is entitled to summary judgment on this claim regardless of the admissibility of the testimony of Dr. Theut and Dr. Gold.

3. Failure to Warn

Coloplast argues that Cantrell's failure-to-warn claim fails because Cantrell has not provided admissible specific-causation evidence. As addressed above, under California law, a plaintiff advancing product-liability claims must prove that a defect in the product caused injury. *See Brady*, 194 Cal. Rptr. 3d at 246. Proof of causation must be established "within a reasonable medical probability based upon competent expert testimony." *Jones*, 209 Cal. Rptr. at 460. Here, the Court has excluded the specific-causation testimony of Dr. Theut and Dr. Gold, Cantrell's only specific-causation experts. Without admissible testimony supporting Cantrell's claim that the Restorelle L caused her injury, Cantrell cannot succeed on her failure-to-warn claim as a matter of law. Accordingly, Coloplast's motion for summary judgment as to Cantrell's failure-to-warn claim is granted.

Even if the Court had not excluded the specific-causation testimony of Dr. Theut and Dr. Gold, Cantrell's failure-to-warn claim still fails. "A plaintiff asserting causes of action based on a failure to warn must prove not only that no warning was provided or the warning was inadequate, but also that the inadequacy or absence of the warning caused the plaintiff's injury." *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001), *aff'd sub nom. Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659 (9th Cir. 2004); *accord Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1238 (9th Cir. 2017); *cf. Ramirez v. Plough, Inc.*, 863 P.2d 167, 177 (Cal. 1993) (holding that there was "no conceivable causal connection between the representations or omissions that accompanied the product and plaintiff's injury" because the Spanish-speaking plaintiff did not read the English warning or obtain a translation). "California applies the 'learned intermediary' doctrine which provides that the duty to warn in the case of medical devices runs to the physician, not the patient." *Tapia v. Davol, Inc.*, 116 F. Supp. 3d 1149, 1158 (S.D. Cal. 2015). Under the learned intermediary doctrine, a "manufacturer fulfills its duty to warn if it provides adequate warnings to the physician." *Id.*

Coloplast relies on the deposition testimony of Dr. Larry Bowen, the surgeon who implanted Cantrell's Restorelle L, in support of its argument that a different warning would not have changed the outcome. Dr. Bowen testified that he did not recall reading the instructions for use for the Restorelle L. He further testified, "I never depended upon what the company had to tell me about their product. I researched their product in the medical literature . . . [a]nd used that information to guide my implantation." Because Dr. Bowen did not review the IFU for the Restorelle L, Coloplast has provided evidence

that a different warning would not have changed the outcome. Cantrell provides no evidence to the contrary, beyond an unsupported allegation that Coloplast has a duty to inform the medical community of all known risks and complications of its device. A non-moving party must "demonstrate on the record the existence of specific facts which create a genuine issue for trial." *Krenik*, 47 F.3d at 957 (internal quotation marks omitted). Cantrell has failed to make such a showing. Even if the Court had not excluded the specific-causation testimony of Dr. Theut and Dr. Gold, Coloplast would nonetheless be entitled to summary judgment as to Cantrell's failure-to-warn claim.

ORDER

Based on the foregoing analysis and all the files, records and proceedings herein, **IT IS HEREBY ORDERED**:

1. Defendants' motion to exclude the opinions and testimony of Dr. Garely, (Dkt. 48), is **GRANTED**.

2. Defendants' motion to exclude the opinions and testimony of Dr. Mays, (Dkt. 54), is **GRANTED IN PART AND DENIED IN PART** as addressed herein.

3. Defendants' motion to exclude the opinions and testimony of Dr. Pence, (Dkt. 60), is **GRANTED IN PART AND DENIED IN PART** as addressed herein.

4. Defendants' motion to exclude the opinions and testimony of Dr. Theut, (Dkt. 66), is **GRANTED IN PART AND DENIED IN PART** as addressed herein.

5. Defendants' motion to exclude the opinions and testimony of Dr. Rosenzweig, (Dkt. 72), is **GRANTED IN PART AND DENIED IN PART** as addressed herein.

6. Defendants' motion to exclude the opinions and testimony of Dr. Gold, (Dkt. 78), is **GRANTED IN PART AND DENIED IN PART** as addressed herein.

7. Defendants' motion for summary judgment, (Dkt. 43), is **GRANTED**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: July 18, 2022

s/Wilhelmina M. Wright
Wilhelmina M. Wright
United States District Judge